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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,952	03/06/2006	Ingo Haeberlein	59181US004	8655

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EXAMINER	
MAEWALL, SNIGDHA	
ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
03/29/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/539,952	HAEBERLEIN ET AL.	
	Examiner	Art Unit	
	Snigdha Maewall	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-30,33 and 34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-30,33 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/23/09 and 12/18/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Receipt of applicant's arguments and amended claims filed on 10/23/09 is acknowledged.

Receipt of IDS filed on 10/23/09 and12/18/09 is also acknowledged.

Claims 1-16 remain cancelled, Claims 31-32 have been withdrawn and claims 33-34 are new in this application. Accordingly, claims **17-30 and 33-34** are under prosecution.

The rejections not reiterated herein have been withdrawn in light of applicant's arguments.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 17-26 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 2002/006820. (US 2004/0029171 is the national stage application for this WO reference and is used for translation purposes).

The current claims are directed to a dental material comprising at least one substance whose antibacterial efficacy is formed in the presence of intraoral microbes.

The reference teaches an invention that relates to a method for analysis and a device for carrying out the method for analysis of saliva and is suitable for the detection of caries-causing and/or periodontitis-causing bacteria found in saliva and/or gum pocket fluid [0001]. The invention includes the use of a device containing a composition which comprises an indicator substance [0011]. The indicator substance includes all substances which are suitable for generating a detectable signal with another substance [0032] such as, *inter alia,* methylene blue and benzofurazan derivatives [0033]. The indicator substances can be bonded covalently to, inter alia, polyethers. The composition of the invention may also include hydrogen peroxide, a known initiator [0133].

Although defined in the reference as indicator substances, it is submitted that when methylene blue and the benzofurazan derivative come into physical contact with the microbe or microbe enzyme in the saliva, then the bacteriostatic or bactericidal efficacy is formed since both methylene blue and the benzofurazan derivative are also antibacterial agents[1,2].

Applicant's Arguments

[1] Kondyukov et al. (Russian Journal of Organic Chemistry; Volume 43, Number 4 / April, 2007:635-636) - disclosing that benzofurazan derivatives possess antibacterial properties (1st page, 1st column, 1st).

Applicant's arguments filed 10/23/09 have been fully considered but they are not persuasive.

Applicants argue that the Examiner has not identified within Wagner et al. a dental material that includes at least one substance whose bacteriostatic and/or bactericidal efficacy is formed in the presence of intraoral microorganisms. Specifically, the Examiner has improperly equated a substance having antimicrobial properties (without regard for the presence of intraoral microorganisms) with a substance whose bacteriostatic and/or bactericidal efficacy is formed in the presence of intraoral microorganisms. It is submitted that whatever bacteriostatic and/or bactericidal efficacy is present in methylene blue and benzofurazan, it is present in the structure of the compounds, and the Examiner has failed to identify any disclosure of Wagner et al. that the efficacy of the cited compounds is formed in the presence of intraoral microorganisms.

In response to applicant's argument that Examiner has not identified within Wagner et al. a dental material that includes at least one substance whose bacteriostatic and/or bactericidal efficacy is formed in the presence of intraoral microorganisms recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

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[2] US 2006/0177477 - disclosing in [0018] that one photo-oxidant that has been shown by the inventors to have excellent antimicrobial properties is methylene blue.

In the instant case prior art teaches dental material which is benzopheron and methylene blue and both of which have antibacterial properties, as such having bacteriostatic or bactericidal efficacy will be intrinsic to the composition. Therefore the arguments are not persuasive.

4. Claims 17-20, 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by USP 5,603,921.

The reference teaches a medicated dental floss with an antimicrobial agent incorporated therein, as a result of the flossing action; the antimicrobial is deposited to the interdental area of the teeth. Fabricating the dental floss comprises dissolving a predetermined amount of chlorhexidine gluconate in a polyethylene glycol base (claim 1). The bacteriostatic/bactericidal efficacy of chlorhexidine is formed when it physically contacts the intraoral bacteria. The substance would naturally be enriched as claimed in claim 19 and 20.

Applicant's Arguments

Applicant's arguments filed 10/23/09 have been fully considered but they are not persuasive.

Applicant argues that Bowen fails to disclose a substance whose bacteriostatic and/or bactericidal efficacy is formed in the presence of intraoral microorganisms. Rather, Bowen's antimicrobial (e.g., chlorhexidine) has efficacy that is formed before being in the presence of intraoral microorganisms.

In response to applicant's argument that Bowen fails to disclose a substance whose bacteriostatic and/or bactericidal efficacy is formed in the presence of intraoral microorganisms, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, Bowen discloses antimicrobial agent chlorhexidine and thus the property of having bactericidal efficacy will be intrinsic to the antibacterial compound absent evidence to contrary.

5. Claims 17-20, 22, 23 and 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/48766, presented in IDS.

Polymerizable dental materials having an antimicrobial effect are provided. These include dental materials such as protective dental varnishes, composites, compomers, fissure sealants, dental cements, dental bonding agents and similar materials, and containing triclosan (abstract).

The dental materials according to the invention preferably contain a matrix of curable or hardenable resin material or materials. Such materials include for example, methacrylate compounds, urethane compounds and the like. Any conventional dental resin or curable dental matrix material is within the scope of the invention. The dental materials may also contain fillers, fluoride, stabilizers, initiators, solvents and other substances conventionally used in dental materials (paragraph bridging pages 6 and 7).

In the curable dental materials described in this invention, the antimicrobial agent **triclosan** is embedded in a polymeric matrix. This provides the dental materials with a long-lasting antimicrobial effect as the triclosan cannot leach out of these materials quickly (page 7, last paragraph).

Example 3 teaches an example of the invention which comprises 2%, 4%, 6%, 8%, 10% or 15% Triclosan, 4.8 % PENTA (polymerizable material) and 0.2 wt% camphorquinone (initiator).

The substance would naturally be enriched as claimed in claim 19 and 20.

Applicant's Arguments

Applicant's arguments filed 10/23/09 have been fully considered but they are not persuasive.

Applicants argue that Pflug et al. is acknowledged at page 2, lines 1-6 of the Specification (Substitute Specification (clean copy)), which states that the use of triclosan in dental materials is limited in time since the triclosan is dissolved and moved away as a function of its initial concentrations and the saliva flow. Triclosan is a di-phenylether substance bearing three chloro substituents and one hydroxy group. Thus, besides the hydroxy group there is no reactive substituent present and the substance remains stable especially in the oral environment (as confirmed by WO-98/48766; page 4, lines 3-5). The antimicrobial activity of triclosan is caused by the structure as it is. Moreover, triclosan is said to have low water solubility (WO-98/48766; page 6, lines 1-4). In direct contrast, the present claims recite at least one substance whose

bacteriostatic and/or bactericidal efficacy is formed in the presence of intraoral microorganisms. For example, if taurolidine is used instead of triclosan, then a more efficient and completely different manner of antimicrobial reactivity can be achieved. Taurolidine contains 4 (basic) amino groups, 2 sulfur atoms and is a reactive molecule which "decomposes" during reaction and releases formaldehyde, which is assumed to be the antimicrobial and reactive substance. Taurolidine is also water-soluble (see "Taurolidine sc-202827," Santa Cruz Biotechnology, Inc., retrieved from the internet on Sept. 25, 2009, /www.scbt.com/datasheet-202827.html>, 1 page, attached as Exhibit A). Thus, from a chemical perspective, the structure and reactivity of the presently claimed substances (e.g., taurolidine) cannot be compared with the structure and reactivity of triclosan. As can be taken from the description and especially from the examples of the present Specification, it has been found that the presently recited substances (e.g., taurolidine) can be incorporated into various dental materials containing polymerizable components and their respective initiators.

This is surprising. For example, with respect to silicones (typically curing in the presence of a platinum catalyst), the person skilled in the art would expect that the platinum catalyst is damaged either by the nitrogen atoms or the sulfur atoms being present in the taurolidine molecule (see, e.g., Example 1). The same holds true with respect to polyether impression materials. Those materials cure cationically. The initiator basically generates H+ ions. It is surprising that the curing mechanism still functions despite the fact that taurolidine contains basic nitrogen atoms (see, e.g., Example 2). Finally, in view of the fact that triclosan has a low water solubility and

taurolidine has a good water solubility, the person skilled in the art would not be motivated to incorporate this substance into the material described in Pflug et al., because the skilled person would expect that this substance is released from the dental material rather quickly, which would be counterproductive in view of the effect which is intended to be achieved by Pflug et al.

These arguments are not persuasive. First, Taurolidine is not recited in rejected claims therefore the arguments do not commensurate with the scope of rejected claims. Claims are given broadest reasonable interpretation during prosecution, therefore triclosan which is an antibacterial compound reads on the claimed dental material substance which provides bactericidal efficacy and property of such substance is intrinsic to the compound. In response to applicant's arguments that it has been found that the presently recited substances (e.g., taurolidine) can be incorporated into various dental materials containing polymerizable components and their respective initiators, the Examiner points out that the mechanism by which taurolidine reacts and the discussed advantages of curing mechanism are not reflected in the rejected claims.

Additionally, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., taurolidine and the benefits associated with taurolidine) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 27 and 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/48766 in view of USP 4,096,241.

The disclosure of the primary reference is outlined *supra*. It does not expressly teach taurolidine.

The secondary reference discloses preparations for the treatment and for prophylaxis of tooth and gum infections (col. 1, ll. 4-6). The preparation effectiveness is due to the unique action of the compounds concerned not only against bacteria but also against the toxins produced by the bacteria. The antimicrobial of choice is taurolidine in view of its extremely low toxicity over long periods of time (col. 1, ll. 65-68).

Generally, it is prima facie obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended purpose. *MPEP § 2144.07.* Accordingly, it would have been obvious to use taurolidine of the secondary reference as the antimicrobial agent of the primary reference. The motivation would be the reasonable expectation of making the polymerizable dental materials of the primary reference and maintaining antimicrobial properties by using another known antimicrobial agent. Additional motivation would have been to use an antimicrobial known to have low toxicity over long periods of time.

Applicant's Arguments

Applicant's arguments filed 10/23/09 have been fully considered but they are not persuasive.

Applicants argue that combining Pflug et al. and Geistlich et al. is not obvious. Geistlich et al. disclose oral care compositions, but not those with curable or hardenable compositions. One of skill in the art would not have had a reasonable expectation of success. For example, one of skill in the art would not have expected that the curable

compositions of Pflug et al. would still be curable and that the curing mechanism would not be negatively affected by the addition of Geistlich et al.'s taurolidine. Moreover, one of skill in the art would not have expected that taurolidine would still be effective when added to the curable compositions of Pflug et al.

Applicant's arguments are not persuasive because Geistlich has been cited for an antibacterial substance such as taurolidine and whether being used with curable and hardenable compositions is an intended use which does not hold patentable weight wherein the claims are drawn to dental material. Additionally such limitations are not reflected in claims. Claims are drawn to dental material and application of dental material is an intended use which does not hold patentable weight. Prior art teaches taurolidine, an antimicrobial agent and motivation to combine with primary reference is for its low toxicity properties as discussed in the rejection above. Prior art teaches compatibility for oral applications, therefore one of ordinary could utilize the compound taurolidine in dental curable composition. The art pertains to same field of endeavor and is an analogous art and thus utilization of taurolidine for bactericidal efficacy would have been obvious to one of ordinary skill in that art at the time of instant invention.

Applicant further argues that it may not be necessarily concluded that if one takes a substance (e.g., taurolidine) that has been used in non-curable compositions (e.g., mouthwashes, dentrifices, etc.), then that substance can also be used in curable compositions. When a substance is put into a curable composition, the substance will typically remain within the composition, especially if the composition is cured. Thus, it would be expected that the efficacy of the substance would be dramatically reduced (e.g., as compared to the substance in a liquid composition, such as mouthwash). Surprisingly, Applicants found that a substance (e.g., taurolidine) whose bacteriostatic and/or bactericidal efficacy is formed in the presence of intraoral microorganisms may be incorporated into a curable composition. Moreover, the structure of Geistlich et al.'s taurolidine is very much different from that of Pflug et al.'s triclosan and, thus, it may be assumed that the mechanism used by triclosan to kill germs may be different from that used by taurolidine. The Examiner, in simply stating that it would have been obvious to exchange Pflug et al.'s triclosan with Geistlich et al.'s taurolidine, has not provided

adequate and proper reasoning sufficient to establish a primafacie case of obviousness. Once the solution to a problem is known, one can be tempted to import hindsight and allege it is obvious. Thus, Applicants respectfully submit that the Examiner's combination of Pflug et al. in view of Geistlich et al. must have been as a result of improper hindsight analysis.

These arguments are not persuasive. Instant claims are drawn to dental material and application of dental material is an intended use which does not hold patentable weight. Claims recite dental material which can be broadly interpreted as mouth rinse or mouthwashes or dentifrices. The claims do not recite method of using taurolidine in curable composition; the claims are drawn to dental material and Prior art teaches taurolidine, an antimicrobial agent and motivation to combine with primary reference is for its low toxicity properties as discussed in the rejection above. Prior art teaches compatibility for oral applications, therefore one of ordinary could utilize the compound taurolidine in dental curable composition. The art pertains to same field of endeavor and is an analogous art and thus utilization of taurolidine for bactericidal efficacy would have been obvious to one of ordinary skill in that art at the time of instant invention. Therefore the argued surprising utilization of taurolidine in curable composition is an intended use wherein the claims are drawn to a dental material.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a

reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

8. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is 571-272-6197. The examiner can normally be reached on Monday - Friday from 8:30 - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/
Examiner, Art Unit 1612
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